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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/609,027	06/29/2000	Wayne A. Hendrickson	50950/JPW/EMW	1817

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John P. White, Esq.
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER

SHEINBERG, MONIKA B

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/609,027

Applicant(s)

HENDRICKSON ET AL.

Examiner

Monika B Sheinberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 and 29-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 June 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group IV (claims 15-28) in Paper No. 9, filed: 04 June 2001, is acknowledged. The traversal is on the ground(s) that the groups are not independent and distinct, and have no burden of search. The argument is found non-persuasive because the groups are distinct and the burden of search was established in the office action mailed 08 May 2001. Please see MPEP 802.01:

The law has long been established that dependent inventions (frequently termed related inventions) such as used for illustration above may be properly divided if they are, in fact, "distinct" inventions, even though dependent.

Applicant elected a species with traverse for Group IV in Paper No. 11, filed: 05 October 2001. The species restriction of SEQ ID NO: 1 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the species election, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-47 are pending. Claims 1-14 and 29-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No.'s 9 and 11.

Drawings Notice

Applicant is hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached to the back of the PTO-948, entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". Due to the above notification Applicant is required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPA 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

The instant application fails to provide guidance to one of ordinary skill in the art for designing a compound that binds to the stem cell factor (SCF) receptor. The specification in figure 6B discloses a representational structure of the receptor, yet the description utilizes various colors to describe particular regions that are not visible in the black and white prints that

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are part of the application. In addition, even if the color was visible and the regions notable, the structure would not be reproducible. The specification does not provide or suggest the crystal structure of the SCF receptor that is reproducible to enable one of ordinary skill in the art to know how to design a compound by the steps described that will bind to its binding site. The specification lacks guidance in the generation of the structure. The examples provided are a description of the SCF and methods of mimicking the SCF structure in order to potentially bind to the SCF receptor. None of the examples provide a description of the SCF receptor. The design method claimed relies upon the three-dimensional structure of the SCF and not the SCF receptor. Determining compounds that bind to the SCF have no indication of whether or not they will bind to the SCF receptor. While working examples are not, per se, required, the specification must provide adequate guidance such that one of skill in the art could practice the invention without undue experimentation. Given the lack of descriptive working examples in the specification, and the unpredictability of designing receptor binding compounds, the specification, as filed is not enabling for the method of designing a compound capable of binding to the receptor site of the SCF receptor as claimed.

In addition the specification fails to provide guidance to one of ordinary skill in the art to generate each and every crystal structure for the "portion/fragment" (line 7) of the SCF polypeptide. The specification does not provide or suggest the resolutions of each and every possible crystal structure to enable one ordinary skill in the art to know how to reproduce these portion or fragment structures. None of the examples provide a descriptions as to the generation of these crystals. While working examples are not, per se, required, the specification must provide adequate guidance such that one of skill in the art could practice the invention without undue experimentation. Given the lack of descriptive working examples in the specification, and the unpredictability crystallography, the specification, as filed is not enabling for using each and every crystal structure of the portion/fragment of the SCF polypeptide as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 15-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 lacks clarity in the claim language "stem cell factor (SCF) receptor site" in line 2. It is unclear if the receptor site indicates the receptor site of the receptor itself or the receptor site of the stem cell factor. As such claims 16-28 which are dependent from claim 15 are also unclear.

Claim 15 is unclear as to the goal of the method of designing a compound. The body of the method claim has confusing steps as to what is intended to be designed: a compound that binds to the SCF itself in its receptor site binding region; or a compound that binds to the SCF receptor as recited in line 13 of step b. As such claims 16-28 which are dependent from claim 15 are also unclear.

Claim 15 lacks clarity in the claim language concerning the atomic coordinate (lines 7-8) limitations of the claim. It is unclear if the three dimensional SCF structure is limited to the particular crystal atomic coordinates disclosed within the specification; if not, then none of the other crystal structures at their different resolutions are supported by the specification, but the crystal structure of SCF disclosed.

Claim 15 lacks clarity due to the use of the term "entity" in line 12. The metes and bounds of that which defines "entity" are unclear.

Claim 17 and 18 are unclear as to which part of Figure 6, 7A or 7B are being referred to. It is unclear because the figures are described per color-coded regions, yet the figures of the instant application are in black and white.

Claim 19 refers to Figure 10B which recites the limitations F_1 , F_2 , F_3 , etc. There is no antecedent basis for these limitations in the claim.

The term "present" of claim 24 is a relative term the renders the claim indefinite. The metes and bounds of that which defines "present" are unclear.

Claim 25 recites the limitation "the linker" in line 1. There is no antecedent basis for this limitation in the claim.

Claim 25 and 28 recite the limitation "the conjugation moiety" in lines 4-5. There is no antecedent basis for this limitation in the claim.

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Claim Objections

Claims 17-20 are objected to due to the improper incorporation of figures by reference in the claims. See MPEP 2173.05 (s).

Conclusion

No claim is allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

May 19, 2002

Monika B. Sheinberg
Art Unit 1631

MB

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1600
AC11631